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Department of Pathology

May 11, 1981

Mr. James Ramey
Chairman
The Formaldehyde Institute
1075 Central Park Avenue
Scarsdale, NY 10583

Dear Mr. Ramey:

As you know, NIOSH is preparing to release a Current Intelligence Bulletin on Formaldehyde. This Bulletin, in its prepublication form, contains several serious errors and omissions which must be corrected before wide dissemination of this publication begins. I trust that the Formaldehyde Institute shares my concerns.

Specifically, the Bulletin states that its recommendation that formaldehyde be handled as a potential occupational carcinogen is based "primarily" on the CIIT study and is supported by the New York University study. It is totally inappropriate for a regulatory agency to draw conclusions as to carcinogenicity on the basis of preliminary animal test data that have not yet been reported in final form, much less subjected to peer review. Other prestigious international scientific bodies such as European Chemical Industry Ecology and Toxicology Center (ECETOC) and the International Agency for Research on Cancer (IARC) have observed proper scientific procedures and have refused to act on preliminary data. ECETOC, after having reviewed the same data of the CIIT study as NIOSH, stated that:

Completion and evaluation of the remaining experimental work is necessary before conclusions can be drawn from this study, particularly as formaldehyde is a normal metabolic product. The nasal cancers occurred only in concentrations that produce chronic tissue irritation and thus it is considered that no cancer would develop at concentrations which do not give rise to such effects. The observed regression of these changes

following cessation of formaldehyde exposure may also be important in the final evaluation.^{1/}

Even the National Academy of Sciences has said with respect to the CIIT study that "the significance of these preliminary findings can be evaluated only after completion of the study and analysis of the pathologic findings."^{2/}

Moreover, NIOSH has transgressed all scientific protocols by relying on an unpublished scientific study conducted at New York University as support for a preliminary study! Even the Federal Panel expressed serious reservations about this study because the animals were ultimately exposed to bis (chloromethyl) ether (BCME). The Federal Panel said that "It is not certain whether the high nasal cancer evidence is a result of the formaldehyde exposure, the (presumed) BCME exposure or the biological interaction of the two or three components of the gas mixture."^{3/} New York University's Department of Environmental Medicine, under the chairmanship of Dr. Arthur Upton (former Director of the National Cancer Institute), decided that this study by Dr. Sidney Laskin, who died several years ago, was unpublishable because of insufficient controls. This study is being repeated now under the direction of Dr. Ray Albert.

Undoubtedly, NIOSH had to go to extremes in order to find any study to "support the preliminary CIIT data." For the fact remains that the animal studies, other than the CIIT, that have withstood academic-level review, have been negative with respect to formaldehyde exposure. The recent report on Formaldehyde and Other Aldehydes by the National Academy of Sciences reviews these negative animal studies in depth. The lack of a similar discussion in the NIOSH document is a serious omission of such magnitude as to constitute error and be misleading on its face.

Another factor that prevents the Bulletin from being balanced is the failure to discuss any of the epidemiology studies that have been done on workers exposed to formaldehyde. A review analogous to NIOSH's effort was undertaken by the Canadian Health and Welfare Ministry and it reported that "Human epidemiological data thus far have identified no increase in nasal carcinoma in anatomical pathologists and undertakers with occupational exposure to formaldehyde."^{4/} Of course, we acknowledge that more epidemiological studies of the kind recommended by the National Academy of Sciences are desirable and the Formaldehyde Institute has undertaken such studies. However,

^{1/}ECETOC Statement on Formaldehyde, January 30, 1981.

^{2/}NAS, Formaldehyde and Other Aldehydes, p. 7-10, (1981).

^{3/}Report of the Federal Panel on Formaldehyde, p. 30, November, 1980.

^{4/}Final Report of the Department of National Health and Welfare Expert Advisory Committee on Urea Formaldehyde Foam Insulation, p. 6, April 1981.


the fact that 7,000 workers with long term exposures to formaldehyde have already been studied and found to have no higher incidence of nasal and respiratory cancer is a very significant one. It is irresponsible for NIOSH not to mention these facts.

Finally, NIOSH has erred in not mentioning the environmental agents that can modify the human response to formaldehyde exposure. The National Academy of Sciences has quite clearly pointed out that "the presence of environmental agents other than formaldehyde, smoking history, variability of health status, age and genetic predisposition may modify responses to formaldehyde." An adequate evaluation of these factors is critical in order to accurately assess the health risks attributable solely to formaldehyde.

The basic concern with the NIOSH Bulletin is that it is extremely premature because no conclusions can be drawn about the carcinogenic risks to humans exposed to formaldehyde due to the incompleteness of data. NIOSH has further compounded its initial error by picking and choosing which preliminary information it intends to release to the public. Rather than a scientifically balanced approach to the evidence accumulated to date on any health effects associated with formaldehyde exposure, NIOSH has selected questionable New York University and preliminary CIIT data to advocate its premature conclusion that formaldehyde is a carcinogen in humans.

Such precipitous action can no longer be tolerated by society. The public has already suffered through several such cancer scares and the credibility of government and science is at a low ebb with serious counterproductive effects occurring. The disastrous nitrate experience at FDA should have warned agencies of the hazards of government actions based on preliminary animal data that have not been subjected to peer review. In that instance, 10 percent of the entire food supply was jeopardized for two years by FDA's hasty conclusion as to the carcinogenicity of nitrites. Later, it was shown to be in error. In this instance, use of a building block chemical in industries comprising 8 percent of the GNP stands to be jeopardized by NIOSH's action. It is my fervent hope that the Formaldehyde Institute can avert such a disaster for society.

Sincerely


 Harry B. Demopoulos, M.D.
 Associate Professor
 New York University Medical Center